

PTO FAX NO.: 1-703-872-9306
ATTENTION: Examiner Sharon L. Turner

Atty Docket No. 15270J-005913US

Group Art Unit 1647

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EXAMINER Sharon L. Turner **GROUP 1600**

CERTIFICATION OF FACSIMILE TRANSMISSION

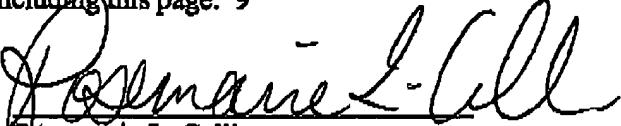
I hereby certify that the following papers in re Application of Dale B. Schenk, Application No. 09/724,953, filed November 28, 2000 for PREVENTION AND TREATMENT OF AMYLOIDOGENIC DISEASE are being facsimile transmitted to the Patent and Trademark Office on the date shown below.

Document(s) Attached

1. Transmittal Form (PTO/SB/21) (1 page);
2. Petition for Extension of Time (PTO/SB/22) (1 page);
3. Fee Transmittal (PTO/SB/17) (1 page, in duplicate); and,
4. Response to Restriction Requirement (4 pages).

Number of pages being transmitted, including this page: 9

Dated: September 26, 2002


Rosemarie L. Celli

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TRANSMITTAL FORM

(to be used for all correspondence after initial filing)

Total Number of Pages in This Submission

Application Number	09/724,953
Filing Date	November 28, 2000
First Named Inventor	Schenk, Dale B.
Group Art Unit	1647
Examiner Name	Sharon L. Turner
Total Number of Pages in This Submission	9
Attorney Docket Number	15270J-005913US

ENCLOSURES (check all that apply)

<input checked="" type="checkbox"/> Fee Transmittal Form (PTO/SB/17) (1 page, in duplicate)	<input type="checkbox"/> Assignment Papers (for an Application)	<input type="checkbox"/> After Allowance Communication to Group
<input type="checkbox"/> Fee Attached	<input type="checkbox"/> Drawing(s)	<input type="checkbox"/> Appeal Communication to Board of Appeals and Interferences
<input checked="" type="checkbox"/> Amendment / Reply (4 pages)	<input type="checkbox"/> Licensing-related Papers	<input type="checkbox"/> Appeal Communication to Group (Appeal Notice, Brief, Reply Brief)
<input type="checkbox"/> After Final	<input type="checkbox"/> Petition	<input type="checkbox"/> Proprietary Information
<input type="checkbox"/> Affidavits/declaration(s)	<input type="checkbox"/> Petition to Convert to a Provisional Application	<input type="checkbox"/> Status Letter
<input checked="" type="checkbox"/> Extension of Time Request (PTO/SB/22) (1 page)	<input type="checkbox"/> Power of Attorney, Revocation Change of Correspondence Address	<input checked="" type="checkbox"/> Other Enclosure(s) (please identify below):
<input type="checkbox"/> Express Abandonment Request	<input type="checkbox"/> Terminal Disclaimer	1. Facsimile Transmittal with Certification (1 page)
<input type="checkbox"/> Information Disclosure Statement	<input type="checkbox"/> Request for Refund	
<input type="checkbox"/> Certified Copy of Priority Document(s)	<input type="checkbox"/> CD, Number of CD(s)	
<input type="checkbox"/> Response to Missing Parts/ Incomplete Application		Remarks The Commissioner is authorized to charge any additional fees to Deposit Account 20-1430.
<input type="checkbox"/> Response to Missing Parts under 37 CFR 1.52 or 1.53		

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

Firm and Individual name	Townsend and Townsend and Crew LLP <i>Rosemarie L. Celli</i>	Reg. No. 42,397
Signature	<i>Rosemarie L. Celli</i>	
Date	September 26, 2002	

CERTIFICATE OF MAILING

I hereby certify that this correspondence is being facsimile transmitted to the Patent and Trademark Office, Fax No. (703) 872-9308 on September 26, 2002

Typed or printed name	<i>Rosemarie L. Celli</i>
Signature	<i>Rosemarie L. Celli</i>
	Date

September 26, 2002

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PA 3252930 v1

FEE TRANSMITTAL for FY 2002

Patent fees are subject to annual revision.

 Applicant claims small entity status. See 37 CFR 1.27

TOTAL AMOUNT OF PAYMENT (\$ 1960)

METHOD OF PAYMENT (check all that apply)

Check Credit Card MoneyOrder Other None
 Deposit Account:

Deposit Account Number 20-1430

Deposit Account Name Townsend and Townsend and Crew LLP

The Commissioner is authorized to: (check all that apply)

Charge fee(s) indicated below Credit any overpayments
 Charge any additional fee(s) during the pendency of this application
 Charge fee(s) indicated below, except for the filing fee to the above-identified deposit account.

FEE CALCULATION

1. BASIC FILING FEE

Large Entity Small Entity

Fee Code	Fee (\$)	Fee Code	Fee (\$)	Fee Description	Fee Paid
101	740	201	370	Utility filing fee	
108	880	208	185	Design filing fee	
107	810	207	285	Plant filing fee	
108	740	208	370	Release filing fee	
114	160	214	80	Provisional filing fee	

SUBTOTAL (1) (\$)

2. EXTRA CLAIM FEES FOR UTILITY AND REISSUE

Total Claims	Extra Claims	Fees from below	Fee Paid
Independent Claims			
Multiple Dependent	X		

Large Entity Small Entity

Fee Code	Fee (\$)	Fee Code	Fee (\$)	Fee Description	Fee Paid
103	18	203	9	Claims in excess of 20	
102	84	202	42	Independent claims in excess of 3	
104	280	204	140	Multiple dependent claim, if not paid	
109	84	209	42	** Reissue independent claims over original patent	
110	18	210	9	** Reissue claims in excess of 20 and over original patent	

SUBTOTAL (2) (\$)

*For number previously paid, if greater; For Reissues, see above

Complete If Known	
Application Number	09/724,953
Filing Date	November 28, 2000
First Named Inventor	Schenk, Dale B.
Examiner Name	Sharon L. Turner
Group Art Unit	1647
Attorney Docket No.	15270J-005913US

FEE CALCULATION (continued)

3. ADDITIONAL FEES						
Large Entity	Small Entity	Fee Code (\$)	Fee (\$)	Fee Description		
		Fee Code (\$)	Fee (\$)			
		105	130	205	65	Burcharge - late filing fee or oath
		127	50	227	26	Burcharge - late provisional filing fee or cover sheet.
		138	130	139	130	Non-English specification
		147	2,520	147	2,520	For filing a request for reexamination
		112	920*	112	820*	Requesting publication of SIR prior to Examiner action
		113	1,840*	113	1,840*	Requesting publication of SIR after Examiner action
		116	110	215	55	Extension for reply within first month
		116	400	216	200	Extension for reply within second month
		117	920	217	460	Extension for reply within third month
		118	1,440	218	720	Extension for reply within fourth month
		128	1,960	228	980	Extension for reply within fifth month
		119	220	218	160	Notice of Appeal
		120	220	220	160	Filing a brief in support of an appeal
		121	280	221	140	Request for oral hearing
		138	1,610	139	1,510	Petition to institute a public use proceeding
		140	110	240	55	Petition to revive - unavoidable
		141	1,280	241	640	Petition to revive - unintentional
		142	1,280	242	640	Utility issue fee (or release)
		143	460	249	230	Design issue fee
		144	620	244	310	Plant issue fee
		122	130	122	130	Petition to the Commissioner
		123	50	123	50	Petitions related to provisional applications
		128	180	126	180	Submission of Information Disclosure Stmt
		581	40	581	40	Recording each patent assignment per property (times number of properties)
		146	740	246	370	Filing a submission after final rejection (37 CFR § 1.129(a))
		148	740	249	270	For each additional invention to be examined (37 CFR § 1.129(b))
		179	740	279	370	Request for Continued Examination (RCE)
		169	800	169	800	Request for expedited examination of a design application
		Other fee (specify)				

*Reduced by Basic Filing Fee Paid

SUBTOTAL (3) (\$1960)

SUBMITTED BY

Complete If applicable						
Name (Print/Type)	Rosemarie Cell	Registration No. (Attorney/Agent)	42,397	Telephone	850-329-2400	
Signature					Date	September 28, 2002

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Fax No. 1-703-872-9300 on September 26, 2002

PATENT
Attorney Docket No.: 15270J-005913US
Client Ref. No.: 209-US-NEW6C3

TOWNSEND and TOWNSEND and CREW LLP

By: Rosemarie L. Celli

Rosemarie L. Celli

#9
M.J.J
9/28/02

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

Dale B. Schenk

Application No.: 09/724,953

Filed: November 28, 2000

For: PREVENTION AND TREATMENT
OF AMYLOIDOGENIC DISEASE

Examiner: Sharon L. Turner

Art Unit: 1647

**RESPONSE TO RESTRICTION
REQUIREMENT**

Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

Applicant files this response to the Restriction Requirement mailed March 26, 2002. A petition to extend the time of response from April 26, 2002 to September 26, 2002 is transmitted herewith. The paragraph numbering of the Restriction/Election of Species Requirement is used in responding to the Examiner's remarks.

¶¶1-4 Applicant elects Group II (claims 11-25).

¶¶5-7 Applicant traverses the Restriction Requirement, and provisionally elects Amyloid β protein precursor (β -APP) of claim 13, and the $A\beta$ peptide of claim 15. Applicant acknowledges the Examiner's requirement to elect a single amyloid component, i.e., applicant must elect one amyloid component, agent, and fibril component from each of claims 13, and 15 of elected Group II. Applicant respectfully points out that claim 13 recites precursor proteins, and not amyloid components. Applicant's provisional election of β -APP is based on the assumption that the Examiner intended to require that Applicant elect a precursor protein, not an amyloid component, from claim 13.

Dale B. Schenk
Application No.: 09/724,953
Page 2

PATENT

The Examiner has effectively required restriction between 17 species generic claim 13, *i.e.*, Serum Amyloid A protein (ApoSSA), immunoglobulin light chain, immunoglobulin heavy chain, ApoAI, transthyretin, lysozyme, fibrogen α chain, gelsolin, cystatin C, Amyloid β protein precursor (β -APP), Beta₂ microglobulin, prion precursor protein (PrP), atrial natriuretic factor, keratin, islet amyloid polypeptide, a peptide hormone, and synuclein; including mutant proteins, protein fragments or peptides thereof. The Examiner has also effectively required restriction between 13 species of generic claim 15, *i.e.*, AA, AL, ATTR, AapoA1, AlyS, Agel, Acys, A β , AB₂M, AScr, Acal, AIAPP and synuclein-NAC fragment.

The Examiner maintains that this requirement is not to be construed as a requirement for an election of species, since each of the compounds recited in alternative form is not a member of a single genus of invention, but constitutes an independent and patentably distinct invention. The only justification or statutory authority put forth by the Restriction Requirement for refusing to examine claim 13 is 35 U.S.C. § 121. However, there is nothing therein to excuse a refusal to examine an elected invention or a generic claim reading thereon.

As a preliminary matter, alleging that a particular claim represents multiple patentably distinct inventions is a *de facto* rejection of the patentability of the claim, because the claim cannot issue as drafted. As the C.C.P.A. noted:

As a general proposition, an applicant has a right to have each claim examined on the merits. If an applicant submits a number of claims, it may well be that pursuant to a proper restriction requirement, those claims will be dispersed to a number of applications. Such action would not affect the rights of the applicant eventually to have each of the claims examined in the form he considers to best define his invention. If, however, a single claim is required to be divided up and presented in several applications, that claim would never be considered on the merits. The totality of the resulting fragmentary claims would not necessarily be the equivalent of the original claim. Further, since the subgenera would be defined by the examiner, rather than by the applicant, it is not inconceivable that a number of the fragments would not be described in the specification.

Dale B. Schenk
Application No.: 09/724,953
Page 3

PATENT

See, In Re Weber, Soder and Boksay 198 USPQ 328, 331 (C.C.P.A. 1978). *See also, In Re Haas* 179 USPQ 623, 624, 625 (*In Re Haas I*) (C.C.P.A. 1973) and *In Re Haas* 198 USPQ 334-337 (*In Re Haas II*) (C.C.P.A. 1978).

Moreover, it has been held that an Examiner may not reject a particular claim on the basis that it represents independent and distinct inventions. *See, In Re Weber, Soder and Boksay, Supra.* The courts have ruled that the statute authorizing restriction practice, i.e., 35 U.S.C. § 121, provides no legal authority to impose a restriction requirement on a single claim, even if the claim presents multiple independently patentable inventions. *See, In Re Weber, Soder and Boksay, In Re Haas I and In Re Haas II.* In the cases set forth above, the courts expressly ruled that there is no statutory basis for rejecting a claim for misjoinder, despite previous attempts by the Patent Office to fashion such a rejection. As noted in *In Re Weber, Soder and Boksay*:

The discretionary power to limit one applicant to one invention is no excuse at all for refusing to examine a broad generic claim-- no matter how broad, which means no matter how many independently patentable inventions may fall within it.

See, In Re Weber, Soder and Boksay at 334.

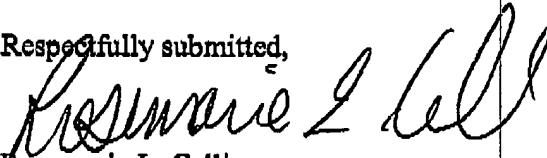
Instead of imposing a restriction requirement on a single claim, the Office may limit initial examination to a reasonable number of species encompassed by the claim. *See, 37 C.F.R. § 1.146.* This practice strikes an appropriate balance between the concerns of the patent office regarding administrative concerns and unduly burdensome examination, and the clear constitutional and statutory rights of an inventor to claim an invention as it is contemplated, provided the dictates of 35 U.S.C. § 112 are complied with. *See, the MPEP at 803.02. See also, In Re Wolfrum* 179 USPQ 620 (C.C.P.A. 1973) and *In re Kuehl* 177 U.S.P.Q. 250 (C.C.P.A. 1973). Unlike a restriction requirement, a species election does not preclude an applicant from pursuing the original form of a claim in subsequent prosecution, nor does it force an applicant to file multiple divisional applications which are incapable of capturing the intended scope of the application.

Dale B. Schenk
Application No.: 09/724,953
Page 4

PATENT

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 650-326-2400.

Respectfully submitted,


Rosemarie L. Celli
Reg. No. 42,397

TOWNSEND and TOWNSEND and CREW LLP
Two Embarcadero Center, 8th Floor
San Francisco, California 94111-3834
Tel: 650-326-2400
Fax: (650) 326-2422
RLC:lah
PA 3251691 v1